



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office  
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Philip S. Johnson, Esq.  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08816

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,254,556

Dear Mr. Johnson :

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,254,556 for a period of one year from the previously extended expiration date. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations). As of August 18, 2003, patent information is required to be submitted on FDA Form 3542 depending on the approval status of the application. Form FDA 3542 is the only form that will be used for Orange Book publication the forms can be found at:  
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048345.pdf>

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at [mary.till@uspto.gov](mailto:mary.till@uspto.gov).

Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

RE: Invega Sustenna®  
FDA Docket No.:

Attention: Beverly Friedman

# UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ortho-McNeil-Janssen Pharmaceuticals, Inc. :  
Request for Patent Term Extension : ORDER GRANTING  
U.S. Patent No. 5,254,556 : INTERIM EXTENSION

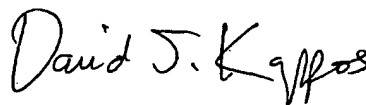
Ortho-McNeil-Janssen Pharmaceuticals, Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,254,556, filed an application for patent term extension under 35 U.S.C. § 156 on August 6, 2009. The original term of the patent expired on October 27, 2009. The patent claims paliperidone palmitate, labeled as the active ingredient in the human drug product Invega Sustenna®, which was approved by the Food and Drug Administration for commercial marketing or use on July 31, 2009. An extension of 1,449 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension under 35 U.S.C. § 156. Because the extended term of the patent would expire before a certificate of patent term extension can be issued, an additional interim extension of the patent term is appropriate.

A second interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,254,556 is granted for a period of one year from the extended expiration date of the patent, i.e., until October 27, 2011.

October 1, 2010

Date



David J. Kappos  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office